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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,604	03/08/2004	Richard S. Bein	H-KN-01944(1) (1847-49)	1765

55748 7590 10/21/2011

Covidien
Attn: IP Legal Department
15 Hampshire Street, Bldg. 4A
Mansfield, MA 02048

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
10/21/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,604	BEIN ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *25 and 27-29* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *25 and 27-29* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/07/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicants arguments filed on 09/08/2011.

- Claims 25 and 27-29 are pending and presented for examination.
- Claims 1-24, 26 and 30 have been cancelled.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 07/07/2011 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (US 2002/0090339 in view of Paterson et al (US 2004/0224864) or Porter et al (US 2004/0197302) **are maintained** for reasons of record in the previous office action filed 06/08/2011.

Claims are drawn to a composition consisting of up to 40 weight percent of ethylene vinyl alcohol copolymer; dimethylsulfoxide; and from 45 to no more than 60 weight percent of tantalum contrast agent having an average particle size of about 5 microns or less; wherein the ratio of ethylene vinyl alcohol copolymer to the tantalum contrast agent is from 0.077 to 0.90; wherein said composition has a viscosity of 150 cSt or higher at 40°C.

Whalen discloses a composition comprising: a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent wherein the weight percent of the biocompatible polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition and wherein the composition has a viscosity of at least about and more preferably at least about 200 cSt at 40°C (abstracl and 0032-0036). The preferred biocompatible polymers include ethylene vinyl alcohol copolymers (0060). The water insoluble contrast agents include tantalum, tantalum oxide, and barium sulfate of particle size of about 10 microns or less and more preferably at from about 1 to about 5 microns (0067 and 0078). The biocompatible solvent includes dimethylsulfoxide,ethanol, acetone and the like (0069). Additional

disclosure includes that sufficient amounts of the contrast agent can be added to the biocompatible solvent to achieve the effective concentration for the complete composition (0077).

Whalen meets the claim limitation but fails to disclose a water-insoluble, biocompatible contrast agent from greater than 40 to 60 weight percent therein.

Patterson discloses a composition comprising biocompatible polymer from about 1 to about 12 weight percent; a biocompatible water-insoluble contrast agent from about 20 to about 55 weight percent and biocompatible solvent (0138, 0193 and 0213). The ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent is within the broad scope of 0.07 or greater when calculated with the recited amounts.

Porter discloses a composition comprising a solution of about 3 to about 12 weight percent of biocompatible prepolymer, about 20 to about 55 weight percent of water-insoluble biocompatible contrast agents and additional biocompatible solvent added to enhance one or more of the properties of the composition e.g., lubricity (0053 and 0069).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a water-insoluble, biocompatible contrast agent from greater than 40 to 60 weight percent into Whalen's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because composition comprising higher concentration of water-insoluble, biocompatible contrast agent can increase the degree of visualizing effect (Patterson, 0073), capable of being monitored during injection into a mammalian subject and reasonably would have

expected success because both Whalen and Patterson's composition is used in the same field of endeavor such as compositions useful in embolizing mammalian blood vessels, to ablate diseased tissue and to treat aneurysms and/or AVMs and Patterson and Porter disclosed using the higher concentration of water-insoluble contrast agents within applicant's range.

Response to Arguments

Applicant's arguments filed on 09/08/2011 have been considered but they are not persuasive.

Applicant argues that Whalen does not teach the use of a contrast agent in an amount from 45 to no more than 60 weight percent in the composition.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413,208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091,231 USPQ 375 (Fed. Cir. 1986). In this case, the Whalen et al. patent is relied upon to show that it is known in the art a composition comprising: a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent wherein the weight percent of the biocompatible polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition and wherein the composition has a viscosity of at least about and more

preferably at least about 200 cSt at 40°C (abstract and 0032-0036), while the Patterson et al ('864) and Porter et al ('302) patent's shows an equivalence of embolic composition comprising a biocompatible water-insoluble contrast agent from about 20 to about 55 weight percent ('864-0213 and '302-0069).

Applicant argues that both Porter and Patterson, which teach the need for employing rheology modifiers in their compositions to obtain a proper viscosity, teach away from the recited composition.

This argument is not persuasive since both Porter and Patterson teaches a composition comprising biocompatible water-insoluble contrast agent from about 20 to about 55 weight percent. The inclusion of additional rheology modifier agents enhances the deliverability of the compositions and high viscosity is also achieved (0029) In doing so, the property of the composition disclosed by Porter and Patterson is not diversified from the instant invention where the viscosity is 150 cSt or higher at 40°C. Thus, the instantly claimed invention is prima facie obvious.

Double Patenting

Claims 25, 27-29 are rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims of 1-6 of US Patent No. 5,667,76i ('767)and claims 1-8 and 16-23 of US Patent No. 5,695,480 ('480) **are maintained** for reasons of record in the previous office action filed on 04/09/2010 and applicants request for abeyance is acknowledged.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

/J. S./
Examiner, Art Unit 1618